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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,236	12/12/2003	Robert R. Steuer	P64272US3	9457

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EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,236	STEUER ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22 and 24-41 is/are rejected.

7)☒ Claim(s) 23 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12122003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 40 is objected to because of the following informalities. In regard to claim 40, step (e) recites the limitations "the tissue's homogeneity" and "the linearity of the distance differentiation" in which there are insufficient antecedent bases. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 22, 24, 28-31, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,136 to Steuer et al. (Steuer) (cited by Applicant) in view of U.S. Patent 4,802,486 to Goodman et al. (Goodman) (cited by Applicant) in view of the European Patent Application 0 444 934 to Hewlett-Packard Company (Hewlett-Packard) (cited by Applicant). Steuer teaches an apparatus that includes providing a blood conduit receiver 6, a radiation–directing means (emitter 1 and 2), and a radiation-detecting means 3. (Fig. 1A of Steuer). The device of Steuer does not teach the use of an energy transducer. Goodman teaches the use of monitoring an EKG waveform for a

more accurate determination by of pulsatile component in blood. (Abstract of Goodman) Goodman teaches that the EKG signal can determine when an arterial pulse is likely to occur and processing the blood oxygen signal during that time period will provide a more accurate measurement. (column 3, lines 20-26 of Goodman). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include synchronizing the pulse waveform with an EKG signal with the oximetry measurement since such synchronization will result in a more accurate measurement. The combination does not teach that the EKG signal is incorporated in the same device as the pulse oximeter. Hewlett-Packard teaches a vital signs monitor in which an EKG, a pulse oximeter, and a blood pressure monitor are incorporated into the same device which fits around a finger. (Fig. 7 of Hewlett-Packard). Hewlett-Packard teaches that this type of coupling of the devices is far simpler than many different connections at different points of the body. (column 5, line 52 to column 6, line 9 of Hewlett-Packard). Although the combination teaches the use of a hematocrit device, the device is also used to determine oxyhemoglobin and reduced hemoglobin. (Abstract of Steuer) which is a form of oximetry measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to use the EKG, the blood pressure, and the pulse oximeter in one device that fits around the finger as disclosed by Hewlett-Packard since the coupling of such devices are simpler than many different connections at different points in the body. The combination teaches operating means (Fig. 1 of Steuer). In regard to claim 24, the combination teaches an EKG detection means. (Abstract and Fig. 1 of Hewlett-

Packard). In regard to claim 28, hematocrit is determined. (Abstract of Steuer). In regard to claims 29-30 and 33, wavelengths of interest include 660, 805, 950, and 1310 nm. (column 8, lines 25-28 of Steuer). In regard to claim 31, the combination teaches that a wavelength in the range of 520 to 600 nm can be used. (claim 28 of Steuer).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 22 and 24-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-20 of U.S. Patent No. U.S. Patent 6,181,958 to Steuer et al. (Steuer '958). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of Steuer '958 claims a method that requires the use of:

(a) a blood conduit receiver for "placing the blood conduit....with the blood flowing in the blood conduit";

(b) a radiation generator (a radiation directing means) for "directing radiation into the flowing blood within the blood conduit...[the]... radiation generator situated within said blood conduit receiver, said radiation defining a directed radiation comprising a first quantity of radiation at a chosen radiation wavelength which, when directed into the flowing blood within the blood conduit, (A) has a first attenuation value which varies with the desired biologic constituent concentration in the flowing blood and (B) has a second attenuation value which varies with the concentration of components other than the desired biologic constituent in the flowing blood, which second attenuation value is at least ten times smaller than said first attenuation value";

(c) a radiation detector (a radiation-detecting means) for "detecting the portion of said directed radiation which passes through both the blood conduit and the flowing blood therein...[the]...radiation detector situated within said blood conduit receiver, said detected portion of said directed radiation comprising a second quantity of radiation at the chosen radiation wavelength"; and

(d) an energy transducer (an energy–detecting means) for "detecting energy from the flowing blood within the blood conduit" and "for measuring the time rate of change of blood volume" and the "energy transducer situated within said blood conduit receiver" and the "energy defining a transduced energy comprising a quantity of energy which when detected from the flowing blood within the blood conduit, has a value which varies with the normalized change of the pulsatile blood".

Steuer '958 does not claim an operating means but Steuer '958 does claim the method step of "operating exclusively on the second quantity of the radiation and the

transduced energy to determine the desired biologic constituent concentration". Steuer '136 teaches controlling and calculating circuitry that would carry out such operations in Figs. 7, 8A-8C, 9A-9D, and 10A-10B of Steuer '136. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the circuitry of Steuer '136 in the claimed invention of Steuer '958 since Steuer '958 teaches that an operating step is carried out and Steuer '136 teaches such circuitry that would be used to carry out that method step. Although Steuer '958 claims a method, the combination includes apparatus elements used to carry out the method of Steuer '958 combination and therefore it would be obvious to one with ordinary skill in the art that to carry out method of Steuer '958 combination would include the apparatus of the present invention.

In regard to claim 24 of the present application, claim 3 of the Steuer '958 combination claims "the step of detecting the transduced energy comprises the steps of: (a) determining the electronic signal generated from the transduced energy; and (b) determining a transduced energy pulsatile value representing the intensities of a pulsatile component of the transduced energy at discreet time intervals during the pulse" and one with ordinary skill in the art would understand that the energy transducer of claim 1 of Steuer '958 must include components capable of carrying out these functions.

In regard to claim 25 of the present application, claim 4 of the Steuer '958 combination claims "(a) mathematically operating on the second quantity of the radiation such that the time derivative of the pulsatile intensities is normalized by the average

intensity over the pulse interval followed by a distance derivative of that quantity to produce a value proportional to $\partial\alpha/\partial t$; and (b) mathematically operating on the second quantity of the radiation such that the logarithm of the intensity is distance differentiated to produce the value α" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out these functions.

In regard to claim 26 of the present application, claim 5 of the Steuer '958 combination claims "the step of performing the time derivative of the normalized pulsatile transduced energy to obtain the value $\partial X_b \partial t$, where X_b is the fractional volume of blood per total tissue volume and t is time" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 27 of the present application, claim 6 of the Steuer '958 combination claims "the step of mathematically solving the relationship $K_b=B\cdot(\alpha\cdot\partial\alpha/\partial t)/(\partial X_b/\partial t)$ with a polynomial function or empirically determined value, where K_b is the macroscopic absorption coefficient for whole blood, α is the bulk attenuation coefficient of the tissue sample, t is time, and X_b is the fractional volume of blood per total tissue volume" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 28 of the present application, claim 7 of the Steuer '958 combination claims "the desired biologic constituent comprises hematocrit or hemoglobin".

In regard to claim 29 of the present application, claim 8 of the Steuer '958 combination claims "wherein the first attenuation value is substantially the same amount for oxyhemoglobin and for reduced hemoglobin in the flowing blood and the second attenuation value is at least ten items smaller than said first attenuation value for any competing constituent in the flowing blood" and one with ordinary skill in the art would understand that the radiation generator of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 30 of the present application, claim 9 of the Steuer '958 combination claims "wherein the radiation wavelength is in the range from about 790 nanometers to 850 nanometers" and one with ordinary skill in the art would understand that the radiation generator of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 31 of the present application, claim 10 of the Steuer '958 combination claims "wherein the radiation wavelength is in the range from about 550 nanometers to 600 nanometers" and one with ordinary skill in the art would understand that the radiation generator of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 32 of the present application, claim 11 of the Steuer '958 combination claims "wherein the energy transducer means is a pressure transducer

element, a strain gage element, a piezo electric film element, or a doppler detection element".

In regard to claim 33 of the present application, claim 12 of Steuer '958 claims a method that requires the use of:

(a) a blood conduit receiver for "placing the blood conduit...with the blood flowing in the blood conduit";

(b) a radiation generator (radiation-directing means) for "directing radiation into the flowing blood within the blood conduit...[the] radiation generator situated within said blood conduit receiver...said radiation defining a directed radiation comprising: (i) a first quantity of radiation at a first radiation wavelength which, when directed into the flowing blood within the blood conduit, (A) has a first attenuation value which varies with the desired biologic constituent concentration in the flowing blood and (B) has a second attenuation value which varies with the concentration of components other than the desired biologic constituent in the flowing blood, which second attenuation value is at least ten times smaller than said first attenuation value, and (ii) a first quantity of radiation at a second radiation wavelength, distinct from said first wavelength, which, when directed into the flowing blood within the blood conduit, (A) has a third attenuation value which for varying concentrations in the flowing blood of the desired blood constituent is a non-fixed multiple of said first attenuation value; and (B) has a fourth attenuation value which varies with the concentration of components other than the desired biologic constituent in the flowing blood, which fourth attenuation value is at least ten times greater than said second attenuation value";

(c) a radiation detector for "detecting the portion of said directed radiation which passes through both the blood conduit and the flowing blood therein...[the] radiation detector situated within said blood conduit receiver, said detected portion of said directed radiation comprising: (i) a second quantity of radiation at the first radiation wavelength; and, (ii) a second quantity of radiation at the second radiation wavelength"; and

(d) an energy transducer for "detecting energy from the flowing blood within the blood conduit" and "for measuring the time rate of change of blood volume" and the "energy transducer situated within said blood conduit receiver" and the "energy defining a transduced energy comprising a quantity of energy which when detected from the flowing blood within the blood conduit, has a value which varies with the normalized blood change of the pulsatile blood".

Steuer '958 does not claim an operating means but Steuer '958 does claim the method step of "operating exclusively on the second quantities of the radiations and the transduced energy to determine the desired biologic constituent concentration". Steuer '136 teaches controlling and calculating circuitry that would carry out such operations in Figs. 7, 8A-8C, 9A-9D, and 10A-10B of Steuer '136. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the circuitry of Steuer '136 in the claimed invention of Steuer '958 since Steuer '958 teaches that an operating step is carried out and Steuer '136 teaches such circuitry that would be used to carry out that method step. Although Steuer '958 claims a method, the combination includes apparatus elements used to carry out the method of Steuer

'958 combination and therefore it would be obvious to one with ordinary skill in the art that to carry out method of Steuer '958 combination would include the apparatus of the present invention.

In regard to claim 34 of the present application, claim 13 of the Steuer '958 combination claims "the step of performing the time derivative of the normal pulsatile transduced energy of the second radiation wavelength to obtain the value $\partial X_b \partial t$, which is the time rate of change of blood volume" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 35 of the present application, claim 14 of the Steuer '958 combination claims "the step of solving the relationship $f(H)=G(\alpha \cdot \partial \alpha / \alpha t)$ for the first wavelength divided by $(\alpha \cdot \partial \alpha / \partial t)$ for the second wavelength with a polynomial function or empirically determined value, where H is hematocrit, G is a constant related to bulk tissue absorption and scattering, α is the bulk attenuation coefficient of a tissue sample, and t is time" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out these functions.

In regard to claim 36 of the present application, claim 15 of Steuer '958 claims a method that requires the use of:

(a) a blood conduit receiver for "placing the blood conduit...with the blood flowing in the blood conduit";

(b) a radiation generator (radiation-directing means) for "directing radiation into the flowing blood within the blood conduit...[the] radiation generator situated within said blood conduit receiver, said radiation defining a directed radiation comprising a first quantity of radiation at a chosen radiation wavelength which, when directed into the flowing blood within the blood conduit, (A) has a first attenuation value which varies with the desired biologic constituent concentration in the flowing blood and (B) has a second attenuation value which varies with the concentration of components other than the desired biologic constituent in the flowing blood, which second attenuation value is at least ten times smaller than said first attenuation value";

(c) a radiation detector (radiation-detecting means) for "detecting the portion of said directed radiation which passes through both the blood conduit and the flowing blood therein... [the] radiation detector situated within said blood conduit receiver, said detected portion of said directed radiation comprising a second quantity of radiation at the chosen radiation wavelength"; and

(d) an energy transducer (an energy detecting means) for "detecting energy from the flowing blood within the blood conduit" and "for measuring the time rate of change of blood volume" and the "energy transducer situated within said blood conduit receiver" and the "energy defining a transduced energy comprising a quantity of energy which when detected from the flowing blood within the blood conduit, has a value which varies with the normalized blood volume"

Steuer '958 does not claim an operating means but Steuer '958 does claim the method step of "operating exclusively on the second quantity of the radiation and the

transduced energy to determine the desired biologic constituent concentration". Steuer '136 teaches controlling and calculating circuitry that would carry out such operations in Figs. 7, 8A-8C, 9A-9D, and 10A-10B of Steuer '136. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the circuitry of Steuer '136 in the claimed invention of Steuer '958 since Steuer '958 teaches that an operating step is carried out and Steuer '136 teaches such circuitry that would be used to carry out that method step. Although Steuer '958 claims a method, the combination includes apparatus elements used to carry out the method of Steuer '958 combination and therefore it would be obvious to one with ordinary skill in the art that to carry out method of Steuer '958 combination would include the apparatus of the present invention.

In regard to claim 37 of the present application, claim 16 of the Steuer '958 combination claims "the step of measuring the transduced energy when the blood conduit is blood-filled, then later made blood-less in order to obtain the value X_b, which is the volume of blood per total tissue volume" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 38 of the present application, claim 17 of the Steuer '958 combination claims "the step of determining X_b is accomplished by solving (V_o/V_f)-1 where V_o is the volume of a bloodless finger and V_f is the volume of a blood filled finger" and one with ordinary skill in the art would understand that the operating means of claim

1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 39 of the present application, claim 18 of the Steuer '958 combination claims "the step of determining X_b is accomplished by solving (V_o/V_f)-1 with a polynomial function and the energy transducer is a pressure transducer and where V^o is the volume of a bloodless finger and V_f is the volume of a blood filled finger" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

In regard to claim 36 of the present application, claim 15 of Steuer '958 claims a method that requires the use of:

(a) a blood conduit receiver for "placing the blood conduit...with the blood flowing in the blood conduit";

(b) a radiation generator (a generation-directing means) for "directing radiation into the flowing blood within the blood conduit...[the] radiation generator situated within said blood conduit receiver, said radiation defining a directed radiation comprising a first quantity of a radiation at a chosen radiation wavelength which, when directed into the flowing blood within the blood conduit, (A) has a first attenuation value which varies with the desired biologic constituent concentration in the flowing blood and (B) has a second attenuation value which varies with the concentration of components other than the desired biologic constituent in the flowing blood, which second attenuation value is at least ten times smaller than said first attenuation value";

(c) a radiation detector (a radiation-detecting means) for "detecting the portion of said directed radiation which passes through both the blood conduit and the flowing blood therein using a radiation detector situated within said blood conduit receiver, said detected portion of said directed radiation comprising a second quantity of radiation at the chosen radiation wavelength"; and

(d) a energy transducer (an energy-detecting means) for "detecting energy from the flowing blood" and "for measuring the time rate of change of blood volume" and the energy transducer is "situated within said blood conduit receiver" and the "energy defining a transduced energy comprising a quantity of energy which when detected from the flowing blood within the blood conduit, has a value which varies with the normalized change of the pulsatile blood".

Steuer '958 does not claim an operating means but Steuer '958 does claim the method step of "operating exclusively on the second quantity of the radiation and the transduced energy to determine the desired biologic constituent concentration by quantifying the tissue's homogeneity from the linearity of the distance differentiation". Steuer '136 teaches controlling and calculating circuitry that would carry out such operations in Figs. 7, 8A-8C, 9A-9D, and 10A-10B of Steuer '136. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the circuitry of Steuer '136 in the claimed invention of Steuer '958 since Steuer '958 teaches that an operating step is carried out and Steuer '136 teaches such circuitry that would be used to carry out that method step. Although Steuer '958 claims a method, the combination includes apparatus elements used to carry out the method of

Steuer '958 combination and therefore it would be obvious to one with ordinary skill in the art that to carry out method of Steuer '958 combination would include the apparatus of the present invention.

In regard to claim 41 of the present application, claim 20 of the Steuer '958 combination claims "the steps of: (a) mathematically operating on the second quantity of the radiation wavelength such that the logarithm of the intensity is distance differentiated to produce the value α; (b) mathematically operating on the second quantity of the radiation wavelength such that the time derivative of the pulsatile intensities is normalized by the average intensity over the pulse interval followed by a distance derivative of that quantity to produce a value proportional to ∂α / αt; which is the change in the bulk attenuation coefficient over time; (c) mathematically determining the linearity and deviation of the logarithm of the intensity and the ∂i/∂t)/i values versus distance where i is light intensity and t is time; and (d) mathematically decoupling, isolating, and determining the individual constituent absorptive and scattering coefficients from the values of α (the bulk attenuation coefficient), ∂α /αt and ∂X_b /∂t (the change in blood volume over time)" and one with ordinary skill in the art would understand that the operating means of claim 1 of Steuer '958 combination must include components capable of carrying out this function.

6. Claims 22, 24, 28, 33, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. U.S. Patent 5,499,627 to Steuer et al. (Steuer '627) in view of U.S. Patent

4,802,486 to Goodman et al. (Goodman) (cited by Applicant) in view of the European Patent Application 0 444 934 to Hewlett-Packard Company (Hewlett-Packard) (cited by Applicant). Claim 1 of Steuer '627 claims a system that includes

(a) "a blood conduit receiving means (a blood conduit receiver) for receiving a blood conduit containing the flowing blood of the patient";

(b) "emission means (radiation-detecting means) for directing radiation into the flowing blood within the blood conduit, said emission means being situated within said blood conduit receiving means, said radiation defining a directed radiation comprising: (i) a first quantity of a radiation at a first radiation wavelength which, when directed into the flowing blood in the blood conduit, (A) has a first extinguishment value which varies with the hematocrit in the flowing blood and (B) has a second extinguishment value which varies with the plasma in the flowing blood, which second extinguishment value is at least ten times smaller than said first extinguishment value"; and

(c) "detection means (radiation detecting means) for detecting the portion of said directed radiation which passes through both the blood conduit and the flowing blood therein, said detection means being situated within said blood conduit receiving means, said detected portion of said directed radiation comprising: a second quantity of a radiation at the first radiation wavelength"; and

(d) "calculation means (operating means) for determining the hematocrit of the patient by operating exclusively on the second quantities of the first and second radiation wavelengths".

The claimed device of Steuer does not teach the use of an energy transducer. Goodman teaches the use of monitoring an EKG waveform for a more accurate determination by of pulsatile component in blood. (Abstract of Goodman) Goodman teaches that the EKG signal can determine when an arterial pulse is likely to occur and processing the blood oxygen signal during that time period will provide a more accurate measurement. (column 3, lines 20-26 of Goodman). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include synchronizing the pulse waveform with an EKG signal with the oximetry measurement since such synchronization will result in a more accurate measurement. The combination does not teach that the EKG signal is incorporated in the same device as the pulse oximeter. Hewlett-Packard teaches a vital signs monitor in which an EKG, a pulse oximeter, and a blood pressure monitor are incorporated into the same device which fits around a finger. (Fig. 7 of Hewlett-Packard). Hewlett-Packard teaches that this type of coupling of the devices is far simpler than many different connections at different points of the body. (column 5, line 52 to column 6, line 9 of Hewlett-Packard). Although the combination teaches the use of a hematocrit device, the device is also used to determine oxyhemoglobin and reduced hemoglobin. (Abstract of Steuer) which is a form of oximetry measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to use the EKG, the blood pressure, and the pulse oximeter in one device that fits around the finger as disclosed by Hewlett-Packard since the coupling of such devices are simpler than many different connections at different points in the body. In

regard to claim 24, the combination teaches an EKG detection means. (Abstract and Fig. 1 of Hewlett-Packard). In regard to claim 28, hematocrit is determined. (claim 1 of Steuer). In regard to claim 33, a third and fourth attenuation values are claimed. (claim 1 of Steuer). In regard to claim 36, claim 1 of the Steuer combination includes a blood conduit receiving means (a blood conduit receiver), an emissions means (radiation-directing means), a detection means (a radiation-detecting means), a calculation means (an operating means), and an energy detection means.

Allowable Subject Matter

7. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest that the energy detecting means includes means for determining the intensity of the radiation wavelength and means for determining a radiation wavelength pulsatile value.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer
Assistant Examiner
Art Unit 3736

MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER